

REMARKS

Applicants sincerely thank Examiner Jagoe for her time and attention in the personal interview held on August 13, 2002. Applicants herein incorporate the comments and suggestions discussed in the interview into this Reply to place the application in condition for allowance.

The Examiner is respectfully requested to enter this Reply After Final in that it raises no new issues. Alternatively, the Examiner is respectfully requested to enter this Reply After Final in that it places the application in better form for Appeal.

Status of the Claims

Claims 1-8 and 11-17 are currently pending in the above identified application. No claims have been canceled or added. Claims 1 and 11 have been amended to change "comprising" to "consisting essentially of". Claim 14 has been amended to delete the phrase "in an ointment". A typographical error has been corrected by replacing "l-menthol" with "l-menthol". Additional grammatical errors were corrected. No new matter has been added by the above claim amendments. No new issues are raised by the above claim amendments. Applicants respectfully request that the amendments be entered as the amendments place the claims in condition for allowance.

Objection to the Information Disclosure Statement

The Examiner objects to the IDS filed on November 2, 2001, because allegedly references were filed not in the English language and no translation or English abstract was provided.

Applicants submit that English equivalents of JP A 08-509749 and B 06-67835 were filed in the U.S. Patent Office. Please see the IDS filed November 2, 2001, section III. (d) entitled "Other", where Applicants explain that USP 5,807,571 previously filed is an equivalent of JP A 08-509749 and that USPs 5,364,628 and 5,593,686 are the equivalents of JP B 06-67835. As such, Applicants have complied with the duty of disclosure to the Patent Office and the objection should be withdrawn.

Rejections under 35 USC 112, second paragraph

The Examiner rejects claims 14-16 as indefinite. Applicants amend claim 14 to delete the phrase "in an ointment" from claim 14. As such, the claims are not longer indefinite and the rejection should be withdrawn.

Rejections under 35 USC 102(b)

The Examiner rejects claims 1 and 3-13 as anticipated by Yoshida et al. USP 4,205,685 (Yoshida '685). Applicants traverse the rejection and respectfully request the withdrawal thereof.

The present invention is directed to a migraine-alleviating drug composition consisting of 1-menthol and one or more essential oils as active ingredients in a pharmaceutically base. The composition may be in an ointment or patch form. The present invention is also directed to a method of treating migraine with the claimed drug composition. The present invention does not include a thermogenic sheet in the patch form. The prevent invention also does not include capsaicin or ketorolac. This limitation is denoted by the phrase "consisting essentially of".

Yoshida '685 discloses a thermogenic sheet combined poultice having two portions, namely a thermogenic composition and a heat stable wet pack. The wet pack may contain a medicine. Menthol is disclosed amongst a list of possible medicines. The primary active ingredient in the invention of Yoshida '685 is the heat component.

However, in the present invention, heat is not an essential component and the addition of a heat component may render the present invention inoperable to achieve its intended purpose. One of the merits of the present invention is to give the patient a chilly feeling. Thus, the present invention does not require heat. In fact, it is found that most patients would dislike a heated patch for treating or alleviating migraine symptoms.

As such, Applicants submit that in view of the above amendments changing "comprising" to "consisting essentially of"

Yoshida '685 does not anticipate the present invention and the rejection should be withdrawn.

The Examiner rejects claims 1 and 3-7 and 17 as anticipated by Noda et al. USP 5,519,046 (Noda '046). Applicants traverse the rejection and respectfully request the withdrawal thereof.

Noda '046 discloses a patch composition comprising high-molecular weight substances combined with humectants and water. l-Menthol and peppermint oil and other essential oils are also disclosed. However, Noda '046 is directed to a patch composition wherein ketorolac is the active ingredient.

Applicants submit that in view of the above amendments changing "comprising" to "consisting essentially of" Noda '046 does not anticipate the present invention. The present invention is directed to a migraine-alleviating drug composition consisting of l-menthol and one or more essential oils as active ingredients in a pharmaceutically base. Ketorolac is not an essential element in the present invention. In fact, Noda '046 discloses that Ketorolac is very unstable and incompatible and must be used with specific bases in order to have an efficacious effect. Moreover, it is suggested that ketorolac has many side effects with long term use. The present invention does not employ the use of the combination of the specific base with ketorolac in the specific formulation to be effective. Also, the present invention is intended for long term use. As such, the incorporation of Ketorolac into the present drug

composition compromises its intended use and renders ketorolac ineffective. Thus, Noda '046 does not anticipate the present invention and the rejection should be withdrawn.

The Examiner also rejects claims 1-8 and 14-16 as anticipated by Block et al. USP 6,090,403 (Block '403). Applicants traverse the rejection and respectfully request the withdrawal thereof.

Block '403 discloses a patch and an ointment vaporizing decongestant comprising menthol, a polymeric gum and a polyhydric alcohol. The decongestant composition in Block is in a foraminous carrier. The active ingredient in Block '403, a decongestant, is applied to the foraminous carrier so that the drug is released into the air and inhaled by the patient.

The present invention does not employ such a carrier for releasing the active ingredient into the air for inhalation. As such, the drug composition of Block '403 is different from the drug composition of the present invention. Moreover, there is no mention or suggestion of the alleviation of any migraine symptoms. Block discloses an analgesic effect, but the alleviation of pain effect in Block is due to the alleviation of congestion by inhalation of the decongestant. As such, Applicants submit that the present invention is not anticipated by Block '403 and the rejection should be withdrawn.

Rejection under 35 USC 103(a)

The Examiner rejects claims 1-16 as obvious over Barr et al. USP 6,197,823 B1 (Barr '823). Applicants traverse the rejection and respectfully request the withdrawal thereof.

Barr '823 discloses a drug composition, which has as the active ingredient capsaicin, which has a skin irritation and burning side effect. The composition of Barr '823 is a pain reliever.

The present invention is directed to a migraine-alleviating drug composition consisting of 1-menthol and one or more essential oils as active ingredients in a pharmaceutically base. Capsaicin is not an essential element in the present invention. In fact, Barr '823 discloses that capsaicin is a skin irritant and thus, in order to have an efficacious effect it must be combined with a particular base that alleviates skin irritation. The present invention does not employ the specific bases to prevent skin irritation and burning. Thus, capsaicin would not be effective in the present drug composition because it would cause skin irritation and burning. As such, the incorporation of capsaicin into the present drug composition compromises its intended use and renders the present invention ineffective due to the side effects of the capsaicin. Thus, one of ordinary skill in the art would not be motivated to arrive at the present invention from the disclosure of

Barr because the teachings in Barr are incompatible with the present invention. Thus, the rejection should be withdrawn.

Conclusion

As Applicants have addressed and overcome all rejections in the Office Action, Applicants respectfully request that the rejections be withdrawn and that the claims be allowed.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Kecia Reynolds (Reg. No. 47,021) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

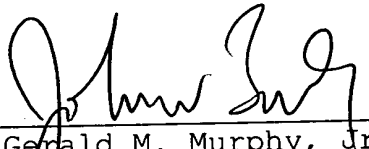
Attached hereto is a marked-up version of the changes made to the application by this Amendment.


Pursuant to the provisions of 37 C.F.R. § 1.17 and 1.136(a), Applicants hereby petition for an extension of one (1) month to September 21, 2002 for the period in which to file a response to the outstanding Office Action. The required fee of \$110.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachment: Version with Markings to Show Changes Made

(Rev. 02/20/02)

VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Twice Amended) A migraine-alleviating drug composition suitable for external application, [comprising] consisting essentially of:

active ingredients consisting of [1-menthol] 1-menthol and one or more essential oils; and
a pharmaceutically acceptable base.

4. (Twice Amended) The drug composition claimed in claim 1, wherein the migraine-alleviating drug is in a patch prepared by mixing [1-menthol] 1-menthol and one or more essential oils as active ingredients into a pharmaceutically acceptable base containing a hydrophilic high-molecular weight compound, a polyhydric alcohol and water.

6. (Twice Amended) The patch claimed in claim 4, wherein the amounts of [1-menthol] 1-menthol and one or more essential oils are 0.01-1% by weight per total weight of the pharmaceutically acceptable base and 0.001-1% by weight per total weight of the pharmaceutically acceptable base, respectively.

11. (Twice Amended) A method for alleviating migraine comprising the step of:

administering to a patient in need thereof an effective amount of a drug composition [containing] consisting essentially of as active ingredients [1-menthol] 1-menthol and one or more essential oils in a pharmaceutically acceptable base [in an effective amount to said patient]; and

wherein said drug composition is dermally administered [dermally].

14. (Twice Amended) The drug composition claimed in claim 1, wherein the migraine-alleviating drug composition is [in an ointment] prepared by mixing [1-menthol] 1-menthol and one or more essential oils as active ingredients into a pharmaceutically acceptable base containing a hydrophilic high-molecular weight compound, a polyhydric alcohol and water.

16. (Twice Amended) The ointment claimed in claim 14, wherein the amounts of [1-menthol] 1-menthol and the essential oil are 0.01-1% by weight per total weight of the pharmaceutically acceptable base and 0.001-1% by weight per total weight of the pharmaceutically acceptable base, respectively.

17. (Amended) The method claimed in claim 11, wherein the amounts of [1-menthol] 1-menthol and one or more essential oils are 0.01-1% by weight per total weight of the pharmaceutically

acceptable base and 0.001-1% by weight per total weight of the pharmaceutically acceptable base, respectively.